CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

63065

APPROVAL LETTER

AADA 63-065

DEC 30 1991

Danbury Pharmacal, Inc.
Attention: Edward M. Cohen, V.P.
131 West Street
Danbury, CT 06810

Dear Sir:

Reference is made to your abbreviated antibiotic drug application dated August 27, 1988 submitted pursuant to Section 507 of the Federal Food, Drug, and Cosmetic Act for Minocycline Hydrochloride Capsules USP, 100 mg.

We acknowledge receipt of your additional submissions dated April 5, May 17, October 15, and November 1, 1991.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Minocycline Hydrochloride 100 mg capsules to be bioequivalent to those of the listed drug MINOCIN (minocycline hydrochloride) 100 mg capsules by Lederle Laboratories.

Any significant change in the conditions outlined in this abbreviated application requires an approved supplemental application before the change may be made, except for changes made in conformance with other provisions of Section 314.70 of the new drug regulations.

Postmarketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80 and 314.81 of the Regulations.

This administration should be advised of any change in the marketing status of this drug.

For Initial Campaigns: We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your immediate advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising and Communications (HFD-240). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

For Subsequent Campaigns: We call your attention to Section 314.81(b)(3) of the Regulations which require that materials for any subsequent advertising or promotional campaign, at the time of their initial use, be submitted to our Division of Drug Marketing, Advertising and Communications (HFD-240) with a completed Form FD-2253.

Sincerely yours,

/S/ - 11/30/91

Roger L. Williams, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: AADA #63-065
DUP/Division File
HFC-130/JAllen
HFD-600/RF
HFD-635/RF
HFD-635/JHarrison/RAdams/11/13/91 R.C. Adams, 11/18/91
HFD-635/MAnderson M. Anderson 11/18/91
R/D initialed by JHarrisor

APPROVAL